FDA 510(k) Premarket Notification

K001738 DEPUY RESTORE ORTHOBIOLOGIC SOFT TISSUE IMPLANT

CLEARED

Dec 27, 2000
203 days to decision

K001738 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k001738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Jun 7, 2000
Decision date	Dec 27, 2000
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**DePuy Orthopaedics, Inc.**
Location	Warsaw, IN, US
Contact	MARCIA J ARENTZ
510(k) history	206 submissions · 204 cleared · 1998-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k001738/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026